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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,545	02/27/2004	Steven W. Ek	ART 03.03	9474

7590 04/04/2007
Grossman, Tucker, Perreault & Pfleger, PLLC
55 South Commercial Street
Manchester, NH 03101

EXAMINER

PRIDDY, MICHAEL B

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/789,545	Applicant(s) EK, STEVEN W.	
	Examiner Michael B. Priddy	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
4a) Of the above claim(s) 22-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date : 12/08/2006; 03/02/2006; 05/02/2005; 09/02/2004; 06/30/2004 & 02/27/2004.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, drawn to an implant, classified in class 623, subclass 16.11.
- II. Claims 22-32, drawn to a method of producing a composite implant, classified in class 424, subclass 423.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make an implant of design different from that of invention I.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Edmond Pflieger on 30/21/2007 a provisional election was made without traverse to prosecute invention I, claims 1-21. Affirmation of this election must be made by Applicant in replying to this Office action. Claims 22-32 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The disclosures of the prior-filed application, Application Nos. 10/373,463; 10/162,533; 10/024,077; 09/846,657 fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. These disclosures do not provide support for the subject matter of the claims. The effective date of the present application pertaining to the claimed subject matter has therefore been considered to be 02/27/2004.

Claim Objections

Claim 2 is objected to because of the following informalities: in line 1, --the— should be inserted between “wherein” and “body portion”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the limitation "said plurality of recesses" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The disclosures of the prior-filed application, Application Nos. 10/373,463; 10/162,533; 10/024,077; 09/846,657, from which Applicant has claimed benefit fail to provide adequate support or enablement in the manner provided by the first paragraph

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of 35 U.S.C. 112 for claims 1-21 of the present application. These disclosures do not provide support for the subject matter of the claims. The effective date of the present application pertaining to the claimed subject matter has therefore been considered to be the filing date of the present application, 02/27/2004.

Claims 1-7, 9-13, 16 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Ogden (US 6,299,645). Ogden teaches an implant 400 comprising: a load bearing surface, said surface comprising a body portion comprising a recess 408 comprising an undercut 406 and an insert 500 at least partially disposed in said recess 408 and comprising a protrusion 505 at least partially received in said undercut 406; further comprising a mounting feature 410; wherein said body portion comprises a metallic material (lines 2-3 of column 5) and said insert 500 comprises a polymeric material (lines 32-33 of column 6).

Claims 11 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Ogden (US 6,299,645). Ogden (alternative interpretation) teaches an implant 400 comprising: an implant body portion comprising at least one recess 408; and an insert 500 disposed in said recess 408; said implant 400 comprising a load bearing surface, said load bearing surface comprising a portion of said body portion and a portion of said insert 500; wherein said body portion comprises a first member comprising an opening 406 and a second member 410, said recess 408 at least partially defined between said first and second members, said insert 500 disposed at least partially (element 505) between said first and second 410 members.

Claims 1, 5, 6, 11, 12, 17 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyde et al. (US 6,599,321). Hyde et al. teach one embodiment of an implant comprising: an implant body portion 424' comprising at least one annular recess; and an annular insert 402B' disposed in said recess; said implant comprising a load bearing surface, said load bearing surface comprising a portion of said body portion 424' and a portion of said insert 402B'; wherein said body portion 424' comprises a metallic body. Hyde et al. also teach another embodiment of an implant comprising an implant body portion 302 comprising a plurality of recesses 306; and a plurality of inserts 18 disposed in said recesses 306.

Claims 11 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Caspari et al. (US 5,263,498). Caspari et al. teach an implant comprising an implant body portion 304 comprising at least one recess 308; and an insert 306 disposed in said recess 308; said implant comprising a load bearing surface, said load bearing surface comprising a portion of said body portion 304 and a portion of said insert 306; wherein said body portion 304 comprises a rim (defined diametrically exterior to recess 310) extending away from said load bearing surface, said rim comprising at least one radial slot 314.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8, 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogden ('645). Ogden teaches an implant 400 comprising: a load bearing surface, said surface comprising a body portion comprising a recess 408 comprising an undercut 406 and an insert 500 at least partially disposed in said recess 408 and comprising a protrusion 505 at least partially received in said undercut 406; further comprising a mounting feature 410; wherein said body portion comprises a metallic material (lines 2-3 of column 5) and said insert 500 comprises a polymeric material (lines 32-33 of column 6). Hence, Ogden teaches all of the limitations of the claimed invention except "said insert comprises a polyvinyl alcohol hydrogel."

It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the insert of Ogden of polyvinyl alcohol hydrogel instead of a generic polymeric material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is 571-272-2243. The examiner can normally be reached on M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael B. Priddy
Michael B. Priddy
March 22, 2007

[Signature]
EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER